510(k) SUMMARY

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OCT 27 2010

K102529

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Date Prepared	August 11, 2010
Summary prepared by:	Sandie Perret, Quality Manager
Device Name	Digital Fluoroscopic X-Ray System
Trade Name	Model D^2RF Digital Dynamic Remote System
Common Name	Image-intensified fluoroscopic x-ray system
Classification	Class: II Product Code: DWB, JAA, IZI Regulation: 21 CFR § 892.1650
Identification of Predicate Devices and Summary of Substantial Equivalence	Canon Dynamic/Static DR Model URS-50RF Fluoroscopic Digital X-Ray System K093688, Virtual Imaging
Device Description	D^2RS is a direct digital dynamic remote-controlled fluoroscopy and radiography system equipped with the latest generation of Canon Flat Panel Detector (FPD). The single FPD can perform both fluoroscopy and radiography and is detachable and portable for direct projections to create a unique and highly versatile 3-in-1 imaging solution. The receptor panel directly converts the X-ray images captured by the LANMIT (Large Area New MIS Sensor and TFT) sensor into a high-resolution digital images. The instrument is suited for use inside a patient environment. This unit converts the X-rays into digital signals. The unit can acquire still and moving images. The system includes a remotely controlled tilting/elevating table.

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(Fluoroscopic Digital X-Ray System)

Intended Use and Indications	The D²RF is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.
Technological Characteristics and Substantial Equivalence	Comparison with the predicate shows the technological characteristics of the D²RF are equal to or better than the predicate device. The units are functionally identical.
Performance Testing/Data	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. Tests include: Performance testing and Software Validation. Electrical safety and Electromagnetic Compatibility testing has been performed. The unit complies with the US Performance Standard for radiographic equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Stephanix Radiological Solutions
% Mr. Daniel Kamm, P.E.
Principal Engineer
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JUL 30 2012

Re: K102529
Trade/Device Name: D^{2}RF Digital Dynamic Remote System
(Digital Fluoroscopic X-Ray System)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IZI
Dated: August 26, 2010
Received: September 2, 2010

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of October 7, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K10_____

Device Name: D^2RF Digital Dynamic Remote System (Digital Fluoroscopic X-Ray System)

The D^2RF Digital Dynamic Remote System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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